(9.5±1.0); standing (8.4±1.8); sleep (7.9±2.3); work-related activities (7.9±2.4); walking (7.8±2.2); sexual activity (7.7±1.7); emotions (7.7±2.4); lifting (7.6±2.5); sitting (7.5±2.0); social activities (7.2±2.4); and traveling (6.8±2.2). **CONCLUSIONS:** Qualitative interviews identified a wide-variety of bothersome symptoms and impacts experienced by patients with cLBP. Patient-reported outcome instruments should measure those experiences, which reflect concepts most relevant to patients. Additional work is needed to assess whether items measuring these concepts are sensitive to change with treatment.

PSY36

CHANGES IN PAIN INTENSITY AND HEALTH RELATED QUALITY OF LIFE (QOL) IN PATIENTS WITH PERIPHERAL NEUROPATHIC PAIN AFTER A SINGLE TREATMENT OF 8% CAPSAICIN PATCH – RESULTS FROM A SWEDISH 12 WEEK PROSPECTIVE OBSERVATIONAL STUDY

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OBJECTIVES: The primary objective was to examine the effect of 8% capsaicin patch on change in "usual pain" using a PNRS (Pain Numeric Rating Scale) from baseline to end of treatment. A secondary objective was to examine utility scores assessed by the EQ-5D. **METHODS:** Adult patients (n=211) diagnosed with peripheral neuropathic pain (excluding diabetes polyneuropathy) were included. The following parameters were investigated over a 12 week follow up period after a single application: - Pain Numeric Rating Scale (PNRS, 0-10) to assess average pain intensity over the last 24 hours, i.e., "usual pain" - EQ-5D - Size of treated area. **RESULTS:** A total of 196 patients completed the study, 66% women and 34% men. Mean age was 54.2 years (range 18-87). At baseline, the "usual pain" intensity was 6.3 (SD 1.8). The mean change of PNRS from baseline to 14 - 90 days post treatment (average pain reduction) was -0.90 (SD 2.08), $p < 0.001$. Maximum mean reduction of "usual pain" at any time point was -1.77 (SD 2.36), $p < 0.001$. Mean EQ-5D health score was 0.29 (SD 0.31) at baseline (range -0.38-1.00). During the post-treatment period the change was 0.26 (SD 0.30), $p < 0.001$. At baseline, 66% of all patients reported "Extreme Problem" in the pain/discomfort dimension and corresponding figures for the post-treatment period was 43%. Median area treated was estimated to 179 cm2(range 3-1120) corresponding to 1.3 patches used per patient per treatment. **CONCLUSIONS:** In this population of patients with peripheral neuropathic pain and a markedly reduced QoL, a single treatment of capsaicin 8% significantly reduced patients' experience of "usual pain" and improved short-term QoL evaluated by EQ-5D.

PSY37

PATIENT-REPORTED OUTCOME (PRO) ASSESSMENTS IN SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

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OBJECTIVES: Review the development and properties of PRO instruments used in clinical trials and observational studies of patients with SLE. **METHODS:** A structured search was conducted to identify published articles in 2005-2011 through key literature databases (EMBASE and MEDLINE/PUBMED). Conference abstracts from targeted rheumatology, outcomes research and quality-of-life (QOL) scientific meetings in 2009-2011 were included. SLE therapy clinical trials within the past five years were identified through the ClinicalTrials.gov database. **RESULTS:** Over 60 different PRO instruments were used in SLE-related research; 7 were lupus specific, 11 assessed general QoL and the rest assessed select (diverse) disease symptoms (e.g., fatigue, pain) or other patient attributes (e.g., satisfaction, adherence). The SF-36, LupusQoL, and LupusPRO were most frequently used in SLE research. These instruments have 36, 34, and 43 items, respectively. All three instruments have a recall period of past four weeks; they demonstrated robust reliability and construct validity when used in SLE patient samples, but generally weak associations (r=0.12-0.29) with SLE disease-activity indices. Validated symptom-specific FACIT-Fatigue scale was also used in some studies to measure this important aspect of patient experience and it correlated with SLE disease-activity indices. Recently, 10 items from the LupusPRO were validated for use as 'Lupus Impact Tracker' (LIT) to retain the reliability and validity of the longer tool while decreasing questionnaire burden. Brief validated instruments used in rheumatic-diseases (e.g., RAPID3: 15 items) are also being studied in SLE. **CONCLUSIONS:** The SF-36, LupusQoL, and LupusPRO are the most widely used validated PRO instruments, but these have a varying degree of questionnaire burden and specificity to SLE symptoms. Shorter versions of validated PROs (e.g., SF-12, LIT) or instruments such as RAPID3 may minimize questionnaire burden. The practicality of these PRO instruments for use in daily practice to discriminate clinically meaningful changes in patient-reported SLE treatment outcomes deserves further investigation.

PSY38

SPONTANEOUS AND PROBED DISEASE-DEFINING CONCEPTS IDENTIFIED THROUGH CONCEPT ELICITATION INTERVIEWS IN CHRONIC LOW BACK PAIN

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OBJECTIVES: To identify symptoms and impacts associated with chronic low back pain (cLBP) that patients report spontaneously and in response to probes during concept elicitation interviews. **METHODS:** Adult patients (18-80 years) with clinical diagnosis of cLBP of non-malignant origin present for at least 3 months with a current pain score ≥4 on a 0-10 numerical rating scale (NRS) were recruited from U.S. and Germany sites. In order to explore relevance of concepts to patients, trained qualitative interviewers conducted semi-structured individual interviews, using open-ended questions to elicit spontaneous reports of symptom/impact concepts, followed by probe questions to assure full coverage of concept domains. Transcripts were coded using Atlas.ti and summarized by distinct concepts. Interview guide notations were used to tag each concept offered by spontaneous versus probed report. **RESULTS:** Forty-three patient interviews were conducted (mean age: 48.6±13.0, 53.5% female, 74.4% -White/Caucasian). Mean (SD) pain NRS score was 6.7(1.3). Spontaneously reported symptoms included: Numbness (51.2% of subjects), Burning (39.5%), and Pain that was Shooting (37.2%), Stabbing (37.2%), and Sharp (37.2%). The low back pain symptoms reported most often in response to probes included Stiffness (55.8% of subjects), Excruciating Pain (41.9%), Pressure (39.5%), Cramping (32.6%), and Pins and Needles (30.2%). Spontaneously reported impacts included interference with: Walking (65.1%), Sitting (62.8%), Exercise (58.1%), Leisure Activities (58.1%), Sleeping (55.8%), Household Chores (53.5%), and Emotional Impacts (48.8%). Impacts reported most often in response to probes included Low Energy because of pain (67.4%), Productivity (65.1%), Financial Impact (46.5%), Driving (39.5%), and Relationships (37.2%). **CONCLUSIONS:** Given the variety of symptoms and impacts described by patients as part of their cLBP experience, those reported spontaneously may be more relevant to patients compared to those reported upon probes. Characterizing patient reported concepts by spontaneous and probed may be useful in increasing the overall sensitivity of the patient reported outcome assessment tool to detect change.

PSY39

VALIDATION OF THE LUPUS IMPACT TRACKER (LIT), A PATIENT-REPORTED OUTCOME (PRO) TOOL, IN A PROSPECTIVE MULTICENTER LONGITUDINAL STUDY OF SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) PATIENTS

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OBJECTIVES: Evaluate the reliability and validity of the LIT, a 10-item PRO assessment of the impact of SLE on the patient's life. Additionally, the acceptability and feasibility of LIT from the patient's and physician's perspectives was assessed. **METHODS:** Baseline data were collected on 325 SLE patients during a clinic visit. Patients completed the LIT, SF-36v2, LupusQoL, and PHQ-9. Both patients and physicians completed a questionnaire on the feasibility/acceptability of LIT. Patients completed the LIT 7-14 days following baseline to assess test-retest reliability. Physicians completed disease activity assessments (SELENA-SLEDAI, BILAG, and SLICC/ACR Damage Index), a physician's global assessment (PGA) and patient's recent flare status. Reliability was evaluated using internal consistency methods (Cronbach's alpha) and test-retest methods (intra-class correlation). Convergent validity was evaluated by correlating LIT scores with scale scores from the SF-36v2, LupusQoL, and PHQ-9. Construct validity was evaluated by comparing mean LIT scores across patients that differed in PGA ratings and presence/absence of a recent flare. ANOVA and Student's t-tests were used to test mean differences in LIT scores across patient groups. It was hypothesized that LIT scores would be lower among patients with lower PGA ratings and no recent flare. **RESULTS:** Internal consistency and test–retest reliabilities of LIT were 0.90 and 0.88, respectively. Convergent validity correlations ranged from -0.63 to -0.75 with SF-36v2 scales, from -0.42 to -0.75 with LupusQoL scales, and 0.75 with the PHQ-9. Mean LIT scores differed as hypothesized across patients with different PGA ratings ($F=5.8$, $df=2$, $p=0.004$). Mean LIT scores differed between patients with and without a recent SLE Flare ($t=2.11$, $p=0.038$). The majority (>70%) of both patients and physicians found LIT to be acceptable and feasible to administer in a clinic setting. **CONCLUSIONS:** The LIT is a reliable and valid instrument for assessing the impact of SLE on patient's functioning and well-being.

PSY40

HEALTH-RELATED QUALITY OF LIFE AND ANNUAL DIRECT MEDICAL COST OF PATIENTS WITH HAEMOPHILIA B IN FRANCE: THE EQOFIX STUDY

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OBJECTIVES: Scarce data is available on the economic burden associated with haemophilia B (HB). The aim of this study was to evaluate in a representative French HB population the impact on health-related quality of life (HRQOL) and to estimate the costs associated with its management. **METHODS:** EQOFIX is a prospective cohort study in patients with moderate and severe HB with one year follow-up. Data collected included: patients' demographic and clinical characteristics, severity status, therapeutical approach, FIX consumption and all other resources used. Two types of HRQOL were used: generic (Kidscreen for children and SF-36 for adults) and specific (QUAL-HEMO, specific to haemophilia patients). The French national health insurance perspective was considered to estimate the average annual cost using official cost database. **RESULTS:** A total of 155 patients had been included by 27 centres, representing a coverage rate of 25% of the French global population suffering from severe and moderate HB: 104 adults (74 severe and 30 moderate) and 51 children (40 severe and 11 moderate). 30.4% of patients re-